

DEC - 8 2000

K003005

510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Application Information:

Date Prepared: September 22, 2000
Submitter: TissueLink Medical Inc.
Address: One Washington Center, Suite 400
Dover, NH 03820
Contact Person: Roberta L. Thompson
Vice President, Clinical, Regulatory Affairs and Quality
Telephone Number: (603) 742-1515 ext. 106
Fax Number: (603) 742-1488

Device Information:

Trade Name: TissueLink Bipolar Forceps
Common Name: Electrosurgical Bipolar Forceps
Classification Name: Electrosurgical cutting and coagulation device and accessories, 21CFR 878.4400

Predicate Devices:

Claim of Substantial Equivalence of the TissueLink Bipolar Forceps is made to:

- Circon Bicap Ablating Forceps BAF-7, K#884306
- United States Surgical Corporation (USSC) Auto Suture* ENDO GIA* II Single Use Stapler, K#900129.

Device Description:

The TissueLink Bipolar Forceps is a sterile, single use device, which employs simultaneous radiofrequency energy and saline irrigation to clamp, coagulate and transect tissue. Transection of tissue is accomplished after clamping and coagulating by use of an integral blade, which is deployed by a thumb fixture on the handle. Radiofrequency (RF) is actuated via a foot pedal. Saline and electrical lines exit at the end of the forceps handle. The tip/blade segment of the device will turn through a radius of $\pm 90^\circ$.

Intended Use:

The TissueLink Bipolar Forceps is a sterile, single-use bipolar electrosurgical device intended to be used in general and thoracic electrosurgical applications for clamping, coagulating and transecting tissue. It is intended for open abdominal and thoracic surgery, laparoscopic procedures, endoscopic procedures and thoracoscopic procedures. The proposed device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Technological Characteristics:

This device has technological characteristics identical to the predicate devices.

Nonclinical Performance:

The performance characteristics of the TissueLink Bipolar Forceps were tested and compared with performance specifications established by TissueLink Medical, Inc. for the device and with commercially available predicate devices.

Clinical Performance:

Clinical testing was not performed on this device.

Conclusions from Nonclinical Tests:

The performance of this device is substantially equivalent to commercially available predicate devices and performs as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Roberta L. Thompson
Vice President, Clinical, Regulatory Affairs
and Quality
TissueLink Medical, Inc.
One Washington Center
Suite 400
Dover, New Hampshire 03820

Re: K003005
Trade Name: TissueLink Bipolar Forceps
Regulatory Class: II
Product Code: GEI
Dated: September 25, 2000
Received: September 26, 2000

Dear Ms. Thompson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

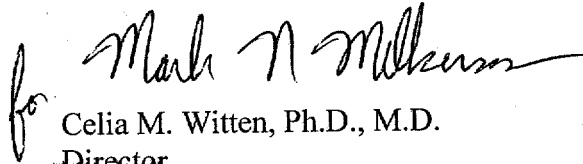
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Roberta L. Thompson

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative

and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for use Statement

Page ____ of ____

510(k) Number (if known): K003005

Device Name: TissueLink Bipolar Forceps

Indications for Use:

The TissueLink Bipolar Forceps is a sterile, single-use bipolar electrosurgical device intended to be used in general and thoracic electrosurgical applications for clamping, coagulating and transecting tissue. It is intended for open abdominal and thoracic surgery, laparoscopic procedures, endoscopic procedures and thoracoscopic procedures. The proposed device is not intended for contraceptive tubal coagulation (permanent female sterilization).

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IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

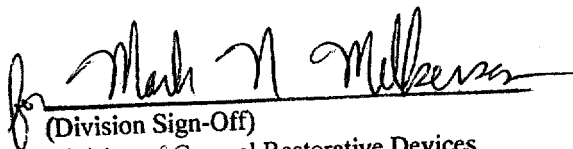
OR

Over-The-Counter

Use _____

(Per 21 CFR 801.109)

Optional Format 1-


(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K003005